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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,218	12/08/2003	Alessandro Luigi Spadini	J6839(C)	4638

201 7590 11/21/2007

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EXAMINER	
RAE, CHARLESWORTH E	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
11/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/730,218	SPADINI, ET AL	
	Examiner	Art Unit	
	Charlesworth Rae	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9 and 11-17* is/are pending in the application.

4a) Of the above claim(s) *18-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9 and 11-17* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments/amendments, filed 8/15/07, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

This action is made final.

Status of the Claims

Claims 1-6, 9, 11-39 are currently pending in this application.

Claims 18-39 are withdrawn.

Claims 1-6, 9, and 11-17 are presented for examination.

Information Disclosure

It is noted that all initialed references listed on Form PTO/SB/08A mailed 7/24/07 have been considered and made on record. However, the unitialed references were not considered and therefore are not of record.

Response to applicant's arguments/remarks

Objection to the Claims

The objection is maintained as the claims are not still in proper form.

It is suggested that this objection may be overcome by either deleting the identifiers preceding each claim limitation e.g. delete a, b, c, d, e, and f, or alternatively, add parentheses to separate the identifiers from the actual claim language e.g. "(a)", "(b)", "(c)", "(d)", "(e)", and "(f)".

Scope of enablement rejection under 112, 1st para

Applicant contends that this rejection should be withdrawn for the following reasons:

1) Amendment of claim 1, to include the limitation of claim 10 and to further recite that the reaction occurs at 25°C, [and which is supported by the specification on page 2, lines 18-22; page 3, line 37; substantial reaction is defined in the specification on page 7, lines 28-30], narrows the scope of the invention.

2) A skilled person would know the identity of other chemical combinations meeting the specific claimed reaction criteria based on the nonlimiting examples of selected reactive chemical combinations disclosed in the specification at page 12, line 18 to page 13, line 8.

3) It is well settled that it is not a requirement to provide an example of every embodiment of the invention encompassed by the claims and broad claims can properly be supported by the disclosure of a single species. In this instance, applicants have described the invention generically and have provided a description of particular examples of the invention. Thus, the particular examples provide for the requisite enablement of the invention, especially commensurate with amended claim 1.

In response, the rejection is maintained as applicants arguments are found to be persuasive overcome the rejection as the specification is not found to enabled for practicing the invention commensurate with the full scope of the claims without undue experimentation for the reasons previously made of record in the Office action mailed 7/24/07 (pages 4-12) and for the additional reasons set forth below:

a) The specification at page 2, para 2: discloses the following:

> Surprisingly it has been found that a skin care or cleansing composition can be formulated which has a substantially solvated or continuous and a substantially unsolvated or discontinuous phase where at least two components of the discontinuous phase may either react with each other when blended with water or where at least one component may itself react with the water so as to provide a unique cleansing, skin benefit, sensory signal or a combination thereof to the user. Such a composition also solves the problem of providing a concentrated cleansing or skin benefit component in a convenient liquid or solid form for consumer use.

However, no specific guidance or direction is provided for someone of skill in the art to reasonably choose any specific combination of a first component and a second component in formulating a skin care or cleansing composition, wherein the composition has a substantially solvated/continuous phase and a substantially insolvated/discontinuous phase, and wherein at least the said first component and said second component are present in the insolvated/discontinuous phase may either react with each other when blended with water or where at least one component may itself react with water so as to provide a unique cleansing, skin benefit effect. Applicant discloses that hydrophobic polymers may be used to adjust the viscosity of the continuous phase (specification page 14 and page 28) and that pH adjusters may be optionally used, for example, to adjust the pH of the separate phases prior to being combined into the inventive product (specification page 28). No specific guidance is provided regarding the viscosity of the encompassed skin care or cleansing compositions, which would vary significantly depending on the specific ingredients or combination of ingredients present in the composition. Further, the term *"a first component being capable of chemically reacting with a second component that is*

different from the first" as recited in claim 1 encompasses a multiplicity of substances, which following interaction with each other would reasonably exhibit different personal effects, including the possibility of undersirable skin irritation. The term *"wherein the first and second components do not substantially react with water or each other until dispersed or dissolved in water at 25°C"* as recited in clam 1, for example, given its broadest reasonable possible interpretation, encompasses a composition wherein the first component is prepared and packaged separately from the second component and blended together by the end user/consumer; this is also supported by the above referenced disclosure regarding the fact that pH adjusters may be optionally used, for example, to adjust the pH of the separate phases prior to being combined into the inventive product (specification page 28). Also, the *term "an anionic surfactant in a concentration of at least 2% by wt. when the at least one stabilizer consists solely of waxy particles, amphipathic compounds or polymers, or a combination thereof"* as recited in claim 1 is still very broad and encompasses any and all polymers, any and all waxy particles, and any and all amphipathic compounds. The term *"an anionic surfactant in a concentration of at least 2% by wt."* is very broad and **is reasonably construed to encompass the anionic surfactant in concentration of at least 2% to 100%.**" In the absence of specific guidance regarding the selection of specific combinations of first component and second component and the viscosity/pH of the encompassed compositions, someone of skill in the art would not be able to predictably practice the instant claimed invention without resorting to extensive experimentation.

Thus, the rejection is maintained.

Rejections under 103(a)

Applicant contends that this rejection should be withdrawn for the following reasons:

1) A proper prima facie case has not been established based on Beerse et al. (US Patent 6,294,186). Beerse et al. at least do not disclose a composition where at least two components of the discontinuous phase may either react with each other when blended with water or at least one component may react with water according to presently amended claim 1. Beerse relates to antimicrobial composition comprising a benzoic acid analog and a dermatologically acceptable carrier for the benzoic acid analog when complexed with metal, wherein the composition has a pH of about 1-7 and is substantially free of a specific organic acid.

2) A proper prima facie case has not been established based on Leyland et al. (GB 2,242,358) in view of Diec et al. (US Patent 6,607,733).

First, Leyland et al. seeks to protect incompatible components within the composition by physically protecting one component within the oily shell of the water-in-oil emulsion, which precludes the existences of an anhydrous continuous phase as required by the instant claims. Second, Leyland et al. do not disclose or suggest the simple two phase composition of the instant claimed invention. Basically, Leyland et al. disclose that certain difficulties may be encountered combining certain ingredients into a single formulation because of their reactivity with each other and that it would be desirable to present interactive components in the same formulation while ensuring that the desired reaction did not occur prematurely at the site of action (page 1, lines 19-26).

Leyland et al. therefore relates to a composition in which a carrier is immiscibly mixed with a water-in-oil- emulsion, wherein the emulsion is stabilized by an emulsifier; and wherein a component which would otherwise interact with an ingredient found in the carrier is located in the internal water phase of the emulsion (page 1, line 30 to page 2, lines 3).

Second, the examiner has failed to meet his burden by presenting the following bare assertions regarding Example 15 of Leyland:

a) sodium lauryl ether sulphate is a compound capable of reasonably generating sulfide ions when reacted wih an alkaline material and water;

b) chlorhexidene gluconate is a compound reasonably capable of generating a peroxide compound;

c) formaldehyde is a compound reasonably capable of producing a gas in aqueous solution when reacted with an acid e.g. citric acid.

Third, Diect et al. do not disclose or suggest at least a composition where at least two components of a discontinuous phase may either react with each other when blended with water or where at least one component may itself react with water.

Fourth, as set forth below:

Applicants have reviewed the following references offered by the examiner to show the general state of the prior art: Remington's (Remington's Pharmaceutical Sciences. 16th ed. (1980); Ha, et al. (US Patent 5,997,887); SaNogueira, Jr., et al. (US Patent 6,174,533); Unger, et al. (US Patent 6,403,065); Robinson, et al. (US Patent 6,492,326); Naser, et al. (US Patent 6,290,943; already made of record by applicant); Oblong, et al. (US Patent 5,939,082); and Patel, et al. (US Patent 6,248,363). Applicant's respectfully submit that neither reference alone or in combination with each other or the other art of record anticipates or renders obvious the instant claims as currently amended.

In response, the rejection is maintained as applicant's arguments are not found to be persuasive for the reasons previously made of record in the Office action mailed 7/24/07 (pages 12-20) and for the additional reasons set forth below:

i) Applicant's traversal argument in connection with the 103(a) rejection based on Beerse et al. is not found to be persuasive. The assertion that Beerse et al. at least do not disclose a composition where at least two components of the discontinuous phase may either react with each other when blended with water or at least one component may react with water according to presently amended claim 1 is not found to be persuasive as evidenced by the below discussion of Chambers et al. (US Patent 5,612,307). The term *"wherein the first and second components do not substantially react with water or each other until dispersed or dissolved in water at 25°C"* as recited in clam 1, for example, given its broadest reasonable possible interpretation, encompasses a composition wherein the first component is prepared and packaged separately from the second component and blended together by the end user/consumer at room temperature (i.e. *25°C*) as evidenced by the teaching of Chambers et al. (US Patent 5,612,307). Also, it is the position of the examiner that the teaching of Beerse as

it relates to antimicrobial composition comprising a benzoic acid analog and a dermatologically acceptable carrier for the benzoic acid analog when complexed with metal, wherein the composition has a pH of about 1-7 and is substantially free of a specific organic acid overlaps with the instant claimed limitations as discussed in the Office action mailed 7/14/07 at pages 12-19.

Chambers et al. teach an aqueous liquid cleansing and moisturising compoisition comprising a surface active agent and a benefit agent in which the surface active agent and benefit agent are separate but combinedly dispensable from a single packing means in a predetermined ratio as discrete domains (abstract). Chgambers et al teach a shower gel formulation with a viscosity in the range of 800 to 15000 mPas measured at a shear rate $10s^{-1}$ and 25°C (col 6, lines 37-50). Chambers et al. teach that where adverse interactions between the benefit agent and surface active are likely to be particularly acute, the benefit agent may be incorporated in a carrier; the benefit agent can be provided in the form of an emulsion as well (col. 3, lines 3-17). Chamber et al. teach that the benefit agents include lipids, alkyl lactates, sunscreens, esters such as isopropyl palmitate and isopropyl myristate, and vitamins; while the preferred benefit agents include silicone oils, gums and modification thereof; esters such as isopropyl palmitate and myristate and alkyl lactates (col. 3, lines 7-15). Chambers specifically teach the following benefit agents: 3,4,4'-trichlor-2'-hydroxydiphenyl ether (referred to as Irgasan DP 300; also know as chlorhexidine gluconate); anti-viral agents; benzoyl peroxide; perfumes; hydroxycaprylic acids; pyrrolidone; carboxylic acids; essential oils; salicyclic acid (col. 6, lines 21-36). Chambers et al. teach that the carrier can, for

example, be a silicone or hydrocarbon oil which is not solubilised/micellised by the surface active phase and in which the benefit agent is relatively soluble (col. 3, lines 9-12). Chambers et al. teach that a surfactant may be added to the phase comprising the surface active agent e.g. swelling clays (e.g. laponite), fatty acids and derivatives thereof (e.g. monoglyceride polyglycol ethers, cross-linked polyacrylates such as Cabopol; acrylates and copolymers thereof; polyvinylpyrrolidone and copolymers thereof; polyethylene imines; salts such as sodium chloride and ammonium sulphate; sucrose esters; gallants (col. 5, lines 12-27). Chambers et al. teach that the some materials can function as both a benefit agent and a thickener even though the benefit and thickening function cannot be provided by the same component; however, where the composition comprises two or more benefit agents one of said benefit agents may also function as a thickening agent (col. 5, lines 58-61).

Based on the teaching of Beerse et al., someone of skill in the art would have been motivated to create the instant inventive concept.

Thus, someone of skill in the art at the time the instant invention was made would have found it obvious to create the instant claimed invention with reasonable predictability as evidenced by the teaching of Chambers et al.

ii) Applicant's traversal arguments in connection with the 103(a) rejection based on Leyland, in view of Diec et al. are not found to persuasive for the reasons previously made of record in the Office action mailed 7/24/07 at page 19, second para to page 20, last para) and for the additional reasons. Based on the open language of instant claim 1, sodium lauryl ether sulphate is a compound that contains sulfur atoms and therefore

is capable of reasonably generating sulfide ions when reacted with an alkaline material and water; chlorhexidene gluconate contains oxygen atoms and is therefore reasonably capable of generating a peroxide compound; while formaldehyde is a compound that contains carbon and oxygen atoms and is therefore reasonably capable of producing oxygen gas or carbon dioxide gas in aqueous solution when reacted with an acid (see The Merck Index. 1989: page 323, abstract 2090; page 662, abstracts 4148-4150; and page 1364, abstract 8587).

Based on the teaching of Leyland, in view of Diec et al., someone of skill in the art would have been motivated to create the instant inventive concept.

Thus, someone of skill in the art at the time the instant invention was made would have found it obvious to create the instant claimed invention with reasonable predictability as evidenced by the above referenced teaching of Chambers et al.

REJECTIONS

Claim Rejection – 35 USC 112 – First Paragraph - Enablement

Claims 1-6, 9 and 11-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the exemplified compositions comprising a dispersed phase including a first component being capable of chemically reacting with a second component that is different from the first component, does not reasonably provide enablement for any and all compositions comprising a dispersed phase including any first component, the first component being capable of chemically reacting with any second component that is different from the first, a continuous phase composed of any substantially anhydrous carrier, at least one of any organophilic

particle stabilizer in the dispersed phase, wherein the first component is substantially unsolvated in any substantially anhydrous carrier, and any anionic surfactant in a concentration of at least 2% by wt. when the at least one stabilizer consists solely of waxy particles, amphipathic compounds or polymers, or a combination thereof. This is a scope enablement rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if its is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth in *In re Wands,* 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman* 230 USPQ 546 (BdApls 1986) at 547 the court cited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence or absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill of those in the art.

The invention in general relates to a skin care or cleansing composition comprising: a) a dispersed phase including an active ingredient (or first component) capable of chemically reacting with a different active ingredient (or second component) that is different from the first second component; b) a continuous phase composed of substantially anhydrous carrier; c) at least one stabilizer contained in the dispersed phase; d) wherein the first component is substantially unsolvated in the carrier; and e) an anionic surfactant in a concentration of at least 2% by wt. When the at least one stabilizer consists solely of waxy particles, amphipathic compounds or polymers, or combination thereof.

The relative skill of those in the art is high, generally that of an M.D. or Ph.D. It is noted that the chemical/pharmaceutical arts is generally unpredictable, requiring each

embodiment to be individually assessed for physiological activity. The more unpredictable an area, the more specific enablement is necessary in order to satisfy the statue. (see *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970)).

The above discussion in connection with the Response to applicant's arguments/remarks with regards to the scope of enablement rejection under 112, 1st para, is incorporated by reference.

Oblong et al. (US Patent 5,939,082) teach compositions comprising a) a vitamin B3 compound, b) a second active, and c) a carrier (columns 2- 30). Oblong et al. teach that the compositions comprise a dermatologically acceptable carrier within which the vitamin B3 is incorporated to enable the vitamin B3 compound and optional actives to be delivered to the skin at an appropriate concentration; the carrier can act as a diluent, dispersant, solvent, or the like for the active(s) which ensures that it can be applied and distributed evenly over the selected target at an appropriate concentration (column 6, lines 57-62). The carrier may contain one or more dermatoligically acceptable solid, semi-solid or liquid fillers, diluents, solvents, extenders and the like; the carrier may be solid, semi-solid or liquid (column 6, line 66 to column 7, line 58). Oblong teaches that preferred carriers comprise an emulsion such as an oil-in-water emulsions, water-in-oil emulsions, and water-in-silicone emulsions (column 7, lines 59-61). Oblong et al. disclose that it would be understood by a skilled artisan that a given component will distribute primarily into either the water or oil/silicone phase, depending on the water solubility/dispersibility of the component in the composition; preferred vitamin B3 compounds distribute primarily into the aqueous phase (column 7, lines 61-66). Oblong

et al. teach emulsions which contain a lipid or oil, and which also contain a humectant, such as glycerin, and an emulsifier (of about 1 to 10% of the weight of the carrier); the emulsion may also contain an anti-foaming agent (col. 8, lines 1-25).Oblong et al. teach a continuous silicone phase containing a polyorganosiloxane oil (col. 8, line 31 to col. 10, line 36); and a dispersed aqueous phase containing water, or a combination of water and one or more water soluble or dispersible ingredients, including thickeners, acids, bases, salts, chelants, gums, water soluble or dispersible alcohols and polyols, buffers, preservatives, sunscreening agents, colorings, and the like (col. 10, lines 36-55). Oblong et al. disclose various dimethicone copolyols and other silicone surfactants useful as emulsifiers, including polydimethylsiloxane polyether copolymers with pendant polyethylene oxide sidechains (col. 11, line 66 to col. 12, line 56). Oblong et al. disclose that various non-ionic and anionic emulsifying agents such as sugar esters and polyesters, alkoxylated sugar esters and polyesters, fatty acid amides, acyl lactylates, soaps, and mixtures of non-ionic/anionic emulsifying agents (col. 12, lines 57-66). Oblong et al. teach that a wide variety of anionic surfactants are useful for use in the composition, including: alkoyl isethionates, and the alkyl and alkyl ether sulfates, soaps (i.e. alkali metal salts, e.g. sodium or potassium salts) of fatty acids (e.g. wherein the fatty acids are derived from natural sources such as palm oil, coconut oil, soybean oil, castor oil; or synthetically prepared) (col. 16, lines 7-48). Oblong et al. further teach that the composition may comprise a wide variety of optional components provided that such optional components are ***physically and chemically compatible with the essential components of the composition and do not unduly impair stability, efficacy of the***

composition (col. 19, line 17 to col. 30, line 9). Oblong et al. teach that the composition is preferably formulated to have a pH of 10.5 or below (col. 19, lines 11-16).

Leyland et al. (GB 2,242,358 A; **already made of record by applicant**), teach cosmetic formulations comprising a cosmetically acceptable carrier immiscibly combined with a water-in-oil emulsion comprising an aqueous phase dispersed within an oil phase by means of an emulsifying agent wherein a component capable of interaction with an ingredient of the carrier is incorporated within the aqueous phase of the emulsion (abstract). Lelyland et al. teach that difficulties may be encountered in combining certain ingredients into a single formulation because some substances useful in cosmetic formulations may interact with other substances (page 1, second para.; and page 3). Leyland et al. disclose specific procedures for preparing the disclosed compositions therein (see Examples 1-18; pages 16-35).

2. The breadth of the claims

The instant claims are relatively broad. For example, claim 1 encompasses any active ingredient as the first component, and all other active ingredients/second components that are different from the first component. Further, the claim limitation *"the first component being capable of chemically reacting with a second component that is different from the first,"* is reasonably construed to mean that the second component may be in the dispersed phase, or continuous phase, or both. Alternatively, the chemical reaction between component 1 and 2 may reasonably not occur in the composition, if for instance, the second component is not a specific component of the composition. Applicant discloses that "chemically reacting as used

herein is defined as but is not limited to gas formation, redox reactions, lysis (e.g. hydrolysis and perhydrolysis), bond cleavage and the like; and does not include reactions or interactions that manifest themselves solely by one or more of the following: 1) color formation or color change, 2) self-polymerization and 3) exothermic or endothermic solvation processes; chemical reactions are not excluded from the invention merely because they are accompanied by color change, self-polymerization, and exothermic or endothermic salvation processes if they also include at least one other definable chemical reaction (para. 0012)." Preferably the first and second components are not encapsulated in a barrier material prior to reaction or at any time (para. 0012). However, in the absence disclosure of the specific reactants (e.g. the first component, and the second component), and the specific conditions favorable for effectuating the chemical reaction between the first component and second component, someone of skill in the art would not be able to reasonably predict where the chemical reaction between the first and second would occur (e.g. in the dispersed aqueous phase vs. continuous phase oily phase), or the pH or temperature or viscosity that could favor a chemical reaction between the first component and second component to practice the instantly claimed invention. The term *"capable"* as defined by the Webster's New Collegiate Dictionary (1981, page 162) means **"having attributes required for performance or accomplishment;"** which is not the same as actually performing a given function i.e. actually causing a chemical reaction between the first component and the second component.

Applicant discloses that the term "substantially anhydrous" as used herein means that the carrier is sufficiently free of water to prevent substantial solvation or reaction with the first component; substantially anhydrous as used herein can also mean that the carrier contains water but that the water is isolated or otherwise prevented from solvating or reacting with the first component (para. 0013).

Applicant asserts that surprisingly it has been found that a skin care or cleansing composition can be formulated which has a substantially solvated or continuous and a substantially unsolvated or discontinuous phase where at least two components of the discontinuous phase may either react with each other when blended with water or where at least one component may itself react with the water so as to provide a unique cleansing, skin benefit, sensory signal or a combination thereof to the user. Such a composition also solves the problem of providing a concentrated cleansing or skin benefit component in a convenient liquid or solid form for consumer use (para. 0005). Also, claim 1, recites the terms *"substantially anhydrous carrier,"* and the term *"the first component is substantially unsolvated in the carrier,"* which are very broad terms as the specific term "substantially" is defined to mean "considerable in quantity" (Webster's New Collegiate Dictionary.1981, page 1153). While claim 2 recites the term *"the second component is substantially unsolvated in the carrier," which is also very broad.* In addition, claim 1 recites the terms *"at least one stabilizer contained in the dispersed phase," which could reasonably be construed to mean one or a million or more stabilizers as the term has no upper limit;* and the term *"an anionic surfactant in a concentration of at least 2% by wt.,"* which given their broadest reasonable

interpretation could reasonably encompass an anionic surfactant in a concentration of 100% of the composition as the claimed concentration range does not have an upper limit. Because the amount of anionic surfactant, number of stabilizers, the specific first component, and specific second component, for example, could reasonably vary widely, the level of predictably in practicing the claimed invention would be greatly diminished.

3. The amount of direction or guidance provided and the presence or absence of working examples

Applicant discloses a number of examples of compositions comprising a Hydrophilic continuous phase and a combination of anionic and amphoteric surfactants (see Example 1, page 28), and other examples, wherein the ingredients of the composition are provided in the form of a list (Examples 1-11; pages 28-40). No specific guidance is provided to for actually making/preparing the instant claimed composition wherein the specific ingredients in the dispersed phase and the continuous phase are specifically delineated, unlike in the case of the prior art (Leyland et al., pages 16-35).

4. The quantity of experimentation necessary

In view of applicant's disclosure, it is reasonable to surmise that the level of uncertainty in the art would require one skilled in the art to conduct more than routine experimentation in order to practice the claimed invention. Thus, based on the known unpredictability of the art (as discussed *supra*) and in the absence of experimental evidence commensurate in scope with the claims, the skilled artisan would not accept

the assertion that the instantly claimed invention could be predictably practiced as claimed.

For the reasons stated above, claims 1-6 and 9, 11-16 are rejected under 35 USC 112, first paragraph, for lack of scope enablement because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with the claims.

Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The above discussion in connection with the Response to applicant's arguments/remarks with regards to the rejection under 103(a) is incorporated by reference.

For purposes of claim rejections under 103(a), the term *"a dispersed phase including a first component, the first component being capable of chemically reacting with a second component that is different from the first,"* as recited in claims 1, is reasonably construed to mean the "discontinuous or external" phase of an emulsion wherein any ingredient present in the dispersed phase is reasonably construed to be the "first component" The *"first component,"* as recited in claim 1, is reasonably construed to be capable of reacting with any other component *"second component,"* that is present in the composition or external to the composition i.e. the first component may reasonably react with a second component e.g. hair or skin, at the point of use of the composition; or may be capable of reacting with a carrier in the composition or different ingredient in the composition.

The term *"substantially anhydrous carrier,"* as recited in claim 1, is reasonably construed to mean any carrier that is not 100% water. The term *"carrier"* given its broadest reasonable interpretation is construed to include any solvent, or diluent, or vehicle that is not comprised of 100% water.

The term *"first component is substantially unsolvated in the carrier,"* as recited in claim 1, is reasonably construed to mean any first component that is completely present or contained in the dispersed phase, wherein the dispersed phase is dispersed within an oil phase by means of an emulsifying agent.

The term *"an organophilic particle,"* as recited in claim 1, is reasonably construed to mean any ingredient that is present in the dispersed phase in the form of a particle i.e. not completely dissolved/solubilized in the dispersed phase, including powders, semi-solids, and colloidal particles (Steadman's Medical Dictionary. 1995; page 1259).

Claims 1-6, 9, 11, and 13-17 are rejected as being unpatentable over Beerse et al. (US Patent 6,294, 186).

Beerse et al. teach compositions comprising water-in-silicone emulsions having a **dispersed phase (**i.e. limitation "a" of instant claim 1) including a **first component** (salicyclic acid; limitation "a" of instant claim 1), and a **second component** (e.g. sodium chloride; limitation "a" of instant claim 1), glycerin and denatured ethanol (i.e. a water soluble **anhydrous fluid/carriers =** substantially anhydrous carrier limitation of item "b" of instant claim 1, and claim 9), and PVP is reasonable construed to be an **organophilic particle/surfactant/stabilizer** (satisfies the "organophilic particle" limitation of claim 1; and the stabilizer limitation of claim 1; and the surfactant limitation "d" of claim 1 (col. 51, Example 16-18). It is noted that the limitation *"an anionic surfactant in a concentration of at least 2% by wt. when the at least one stabilizer consists solely of waxy particles, amphipathic compounds, or a combination thereof,"* recited as item "e" of instant claim 1, is reasonably construed to be essential only *when the at least one stabilizer consists solely of waxy particles, amphipathic compounds, or a combination thereof" (*col. 51, Example 16-18). The first and second components taught by Beerse et al. are reasonably construed to be capable of chemically reacting

via non-polymerization (limitation recited in instant claim 3). The first component is construed to be *"substantially unsolvated in the anhydrous carrier"* in the presence of the PVP (limitation "d" of instant claim 1, and limitation recited in instant claim 2) (col. 51, Example 16-18). However, Example 21-25 teach a liquid handsoap containing anionic surfactants which are reasonably construed to be substantially unsolvated by the anhydrous carrier (e.g. ammonium lauryl sulfate and ammonium laureth-3 sulfate are taught by Beerse; limitation recited in instant claim 11; see col. 53). Beerse et al. teach compositions comprising a **continuous phase** (limitation "b" of instant claim 1; see col. 51, Example 16-18), and **emulsifying agents** (e.g. aluminum starch octenyl succinate; synthetic wax; col. 51, Example 51). Beerse et al. teach composition containing additional ingredients, including pemulen and carbomer (= hydrophilic structuring polymer; see col. 51, Example 14-15); hydrogen peroxide (col. 56, Example 33-35); and petrolatum, propylene glycol, ceteareth-10, cetearyl alcohol, and PEG-330 (see cols. 56-57, Example 33-35). Beerse et al. also teach powders inorganic powders (e.g. gums, chalk, Fuller's earth, kaolin, iron oxide, mica, sercite, muscovite, phlogopie, synthetic mica, lepidolite, biotite, Lithia mica, vermiculite, magnesium carbonate, calcium carbonate, aluminum silicate, starch, smectite clays, alkyl and/or trialkyl aryl ammonium smectites, chemically modified magnesium aluminum silicate, organically modified montmorillonite clay, hydrated aluminum silicate, fumed silica, aluminum starch octenyl succinate barium silicat, calcium silicate, magnesium silicate, strontium silicate etc.), which are reasonably construed to be organophilic particles as these particles are reasonably construed to attract each other through nonpolar mechanisms

(limitation recited in instant claims 6 and 16; see col. 41, lines 1-50; see Steadman's Medical Dictionary (27th edition. http://www.thomsonhc.com/pdrel/librarian/PFActionId/pdrcommon.stedmans.StedmansDocumentAction/DocumentDefinition/pdrcommon.Stedmans/DocumentId/28628/PFPUI/Xm1qVKg1WARh1Q/CS/186AC6); instant claim 6 also recites organophilic silica, organophilic clay. Beerse et al. teach that the **particle size** of the powders are about 0.01 to about 100 microns, which overlaps with the range of particle size recited in instant claims 4-5. Beerse et al. teach structuring agents (limitation recited in claim 12; see col. 17, lines 33-64). The formation of lamellar, hexagonal, or cubic surfactant phases upon contact with water at 25 ° C, as recited in instant claim 12, and the term "wherein the first and second components do not substantially react with water or each other until dispersed or dissolved in water at 25 ° C," are construed to be within the knowledge and skill of an artisan skilled in the art (col. 13, line 10 to col. 14, line 40; and cvol. 17, lines 33-64). Beerse et al. teach that emulsifiers having an HLB value outside of from about 2 to about 14 can be used in combination (col. 15, lines 7-35). Beerse et al. teach compositions comprising a carrier (i.e. the emulsion) wherein the carrier contains an oil (i.e. silicone oil = cylcommethicone), an emulsifier (e.g. cetyl palmitate, or triberhenin), and wherein the stabilizer is an organophilic clay (= hectorite); and the composition contains a total of at least about 10% of reactive dispersed solids by wt., which reasonably overlaps with the limitation of at least about 10% of reactive dispersed solids by wt. recited in instant claim 16, as the term *"at least about 10%"* as recited in instant claim 16, is reasonably construed to encompass amounts above 1%. (see Example 11-13, col. 50). Beerse et

al. teach a continuous phase containing a polyorganosiloxane oil (between about 50% and 99.9% by weight of organosiloxane oil and less than about 50% by weight of a non-silicone oil, which reasonably meet the instant claimed limitation of *"a substantially anhydrous carrier"* as recited, for example, in instant claim 1 (column 12, lines 59-63). Beerse et al. teach that polyalkylsiloxanes useful in the composition include polyalkylsiloxanes with viscosities of from about 0.5 to about 1,000, 000 centisokes at 25 ° C; suitable non-silicone oils for the continuous silicone phase, include e.g. mineral oil,vegetable oils, synthetic oils, and semi-synthetic oils (col. 13, line 10 to col. 14, line 40). Beerse et al. teach a dispersed phase of the composition wherein the aqueous dispersed phase is a dispersion of small aqueous particles or droplets suspended in and surrounded by the continuous silicone phase; the aqueous phase can be water and one or more soluble or dispersible ingredients, including e.g. thickeners, acids, bases, salts, chelants, gums, water-soluble or dispersible alcohols and polyols, buffers, preservatives, sunscreening agents, and colorings (col. 14, lines 41-59). Instant claims 13-15 and 17 recite limitations (e.g. *first component is capable of producing a gas in aqueous solution when reacted with an acid and the second component is an acid or forms an acid in the presence of water; the first component is capable of generating a peroxide compound when dissolved in water; the first component is capable of generating sulfide ions when reacted with an alkaline material in water; the first component is a solid or semi-solid containing dissolved carbon dioxide*), which are reasonably construed to be within the skill and knowledge of an artisan skilled in the art.

For example, Beerse et al. exemplify a composition comprising hydrogen peroxide (limitation recited in claim 14; see Example 33-35, col. 56).

Based on the examples taught by Beerse et al., someone of skill in the art at the time the instant claimed invention was created would have been motivated to create the instant inventive concept, for example, to impart immediate as well as residual effects from a topical composition comprising a first component anti-viral agent and a second component antibacterial agent (col. 1, lines 44-50). Thus, someone of skill in the art at the time the instant invention was made would have deemed it obvious to created the instant claimed invention with a reasonable expectation of success.

The following references are added to show the general state of the prior art: Remington's (Remington's Pharmaceutical Sciences. 16th ed. (1980); Ha et al. (US Patent 5,997,887; SaNogueira, Jr. et al. (US Patent 6,174,533), Unger et al. (US Patent 6,403,065); Robinson et al. (US Patent 6,492,326); Naser et al. (US Patent 6,290,943; **already made of record by applicant**), Oblong et al. (US Patent 5,939,082); and Patel et al. (US Patent 6,248,363)

Claims 1-6, 9, and 11-17 are also rejected under 103(a) as being unpatentable over Leyland (GB 2,242, 358), in view of Diec et al. (US Patent 6,607,733).

Leyland et al. teach cosmetic formulations comprising a cosmetically acceptable carrier immiscibly combined with a water-in-oil emulsion comprising an aqueous phase dispersed (limitation "a" of claim 1) within an oil phase (limitation "b" of claim 1) by means of an emulsifying agent (limitation "c" of claim 1), wherein a component

(satisfies the first component limitation of claim 1) capable of interaction with an ingredient of the carrier (satisfies the second component limitation of claim 1) is incorporated within the aqueous phase of the emulsion (abstract; see page 1, line 5 to page 15, line 22; see also reference claims). Reference Example 15 teach a composition comprising sodium lauryl ether sulphate (limitation "e" of instant claim 1); which is a compound capable of reasonably generating sulfide ions when reacted with an alkaline material and water (limitation recited in claim 15); chlorhexidene gluconate, which is a compound reasonably capable of generating a peroxide compound (limitation recited in claim 14); formaldehyde, which is a compound reasonably capable of producing a gas in aqueous solution when reacted with an acid .e.g. citric acid (limitation recited in claim 13) and the second component is an acid or forms an acid in the presence of water (see reference claim 39). Leyland et al. teach that the emulsion may contain a single emulsifying agent or a mixture of emulsifiers (limitation "c" of claim 1; see also page 4, line 22 to page 6, line 10). Leyland et al. do not specifically teach lamellar, hexagonal, or cubic forms of surfactant phases, however.

Diec et al. (US Patent 6,607,733) teach water-in-oil (W/O) emulsions comprising substituted polysaccharide thickeners, for example, cetylhydroxyethylcellulose, can be advantageously used for physiological activity in the context of cosmetic or pharmaceutical action because of its hydrophobicity (col. 14, lines 22-33). Diec et al. teach compositions comprising 0.001-20% by weight of one or more thickeners in an O/W emulsion can pass through phase inversion by altering the temperature to produce W/O emulsions containing lamellar phases, bicontinuous phases or cubic, hexagonal or

inversely hexagonal phases (limitation recited in claim 12; col. 14, lines 25 -54). The term thickeners is construed to mean a structuring agent, as recited in instant claim 12.

Based on the teaching of the advantageous hydrophobicity produced by the structuring agents taught by Diec et al., someone of skill in the art would have been motivated to combine the teaching of Leyland et al., in view of Diec et al., al. to create a waterproof composition.

Thus, someone of skill in the art at the time the instant invention was made would have deemed it obvious to create the instant claimed invention with reasonable predictability.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

14 November 2007
CER

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PRIMARY EXAMINER